

**UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF PENNSYLVANIA**

IN RE: PHILIPS RECALLED CPAP,)
 BI-LEVEL PAP, AND MECHANICAL)
 VENTILATOR PRODUCTS,) Master Docket No. 21-mc-1230-JFC
 LITIGATION)
) MDL No. 3014
 This Document Relates to: All Actions)
)

**SPECIAL DISCOVERY MASTER’S REPORT AND RECOMMENDATION AND
PROPOSED ORDER RE: SUBPOENA SERVED BY PLAINTIFFS ON EXPONENT, INC.**

I. INTRODUCTION

Plaintiffs and Defendants¹ cross-filed discovery motions relating to a subpoena Plaintiffs served on Exponent, Inc. (“Exponent”) – Plaintiffs seek to compel discovery and Defendants seek entry of a protective order as to the same discovery. Philips retained Exponent to conduct a toxicological risk assessment of patient exposure from degradation of the sound abatement foam (“Foam”) used in the recalled ventilators, BiPAP, and CPAP devices at issue in this litigation (“Devices” or “Recalled Devices”). After conducting its assessment, Exponent prepared certain reports (“Final Reports” or “Reports”). Defendants produced those Reports to the Food and Drug Administration (“FDA”) and made their conclusions accessible to the public on its website. Defendants also produced the Final Reports to Plaintiffs, along with the scientific data and literature referenced in those Reports. The sole issue presented here is whether Philips should also be required to produce all other documents related to the Reports, “including [Exponent’s]

¹ Defendants are Philips RS North America LLC f/k/a Respironics, Inc.; Koninklijke Philips N.V.; Philips North America LLC; Philips Holding USA, Inc.; and Philips RS North America Holding Corporation. “Defendants” and “Philips” as used here may refer to all or a subset of the Defendants.

draft reports and communications between Philips (or its counsel) and Exponent.” *Plaintiffs’ Motion to Compel dated May 1, 2023 (“Ps’ Motion”)* at 1.

II. RELEVANT FACTUAL BACKGROUND

On June 14, 2021, Philips recalled the Devices, citing concerns that: “1) [the Foam] may degrade into particles which may enter the device’s air pathway and be ingested or inhaled by the user, and 2) the [Foam] may off-gas certain chemicals.” Lawsuits commenced soon after.

Philips RS’s litigation counsel, Morgan Lewis & Bockius LLP (“Morgan Lewis”), entered two retention letters with Exponent, one dated September 17, 2021, and the other October 18, 2021. Both were labelled in bold print: “**Prepared at Request of Counsel – Privileged and Confidential.**” The September retention letter reads in part (emphases added):

Thank you for your interest in retaining Exponent to provide technical consultation *related to pending and anticipated federal and state-court litigation involving the . . . Recall Litigation.* . . .

Our proposed scope of services is anticipated to include a review of documents, participation in meetings and related discussions, technical research, testing, and analysis related to the [Recall Litigation]. *Reports summarizing our observations, analysis and opinions will be provided on request.* Exponent understands that this retention is *for the purpose of providing non-testifying consulting expert services* and that Morgan Lewis will advise if it would like to disclose a testifying expert from Exponent, with Exponent’s consent.

Exponent agrees that all communications will be considered protected from disclosure to the maximum extent possible by the attorney-client privilege and the attorney work-product doctrine.

The October retention letter and reads in part (emphasis added):

Thank you for your interest in retaining Exponent to provide technical consultation regarding breathing gas pathway devices manufactured by Philips. . . .

Exponent understands that this retention is *for the purposes of providing non-testifying, consulting expert services to Philips' counsel in anticipation of and in connection with litigation filed against Philips concerning certain devices that have been recalled*. Our proposed scope of services is anticipated to include a review of documents, participation in meetings and related discussions, technical research, testing, and analysis related to the [Recall Litigation]. *Reports summarizing our observations, analysis and opinions will be provided on request.*

Philips ultimately did request Exponent to produce reports summarizing its observations, analysis and opinion and, as stated above, the final versions of those Reports were produced to the FDA as well as Plaintiffs. Most recently, for example, Philips provided to the FDA and produced in discovery a 141-page Final Report dated March 31, 2023 titled *Toxicological Risk Assessment of Type A PE_PUR Foam in Respironics Ventilator, CPAP and BiPAP Devices*. The Report explains and summarizes Exponent's toxicological risk assessment and testing, risk characterizations of Foam particulates and volatile organic compounds, and conclusions. It also includes 28 Tables, 14 Figures, and three Appendices, one of which sets forth the scientific data prepared by approximately five third-party laboratories ("Labs").

III. THE EXPONENT SUBPOENA DISCOVERY DISPUTE

On July 22, 2022, Plaintiffs subpoenaed Exponent seeking material related to testing of Device's Foam. Philips and Exponent assert objections to the subpoena to the extent it seeks materials protected by work product and/or the attorney-client privilege.

Plaintiffs' Position. Plaintiffs argue Exponent is not a non-testifying expert and the draft reports and undisclosed communications are not protected by either the work product doctrine or the attorney-client privilege. Plaintiffs further contend that, by making Exponent's Final Reports public, Defendants waived any privilege as to the entire subject matter of the Reports. Plaintiffs also argue that, even if the work product privilege applies to the draft reports and undisclosed

communications, Plaintiffs meet the “substantial need” and/or “exceptional circumstances” exceptions to Federal Rule of Civil Procedure (“Rule”) 26(b)(3)’s presumption against production of documents prepared in anticipation of litigation, and Rule 26(b)(4)(D)’s presumption against production of documents of a non-testifying expert.

Defendants’ Position. Philips opposes production of the draft reports and the undisclosed communications as protected work product of a non-testifying expert and the attorney-client privilege. Philips maintains its waiver of the Exponent Final Reports and underlying documents was specific to those documents, and not a general subject matter waiver as to all documents related to those Reports, such as draft reports and communications between Exponent and Philips, including its litigation counsel.

IV. WORK PRODUCT

A. Rule 26(b)(4)(D) Applies to this Dispute

The threshold question is whether Rule 26(b)(4)(D) on “Expert Employed Only for Trial Preparation” applies to this dispute. That Rule states:

(D) *Expert Employed Only for Trial Preparation.* Ordinarily, a party may not . . . discover facts known or opinions held by an expert who has been retained or specially employed by another party in anticipation of litigation or to prepare for trial and who is not expected to be called as a witness at trial. But a party may do so only:

- (i) as provided in [Rule 35\(b\)](#) [on Physical and Mental Examinations]; or
- (ii) on showing exceptional circumstances under which it is impracticable for the party to obtain facts or opinions on the same subject by other means.

Lawyers are not scientific experts. Rule 26(b)(4)(D) allows litigation counsel to retain and freely communicate with technical (here, toxicological) experts, and then choose to request – or not to request – these experts to prepare reports for purposes of litigation.

The burden is on Philips, as the party asserting the doctrine, to establish work product protection. *See Conoco Inc. v. U.S. Dept. of Justice*, 687 F.2d 724, 730 (3d Cir. 1982). Philips has met this burden based on the plain language of both retention letters (quoted above at pages 2-3), and the related sequence of event. The letters were executed *after* Philips recalled the Devices and litigation was a reality. Morgan Lewis – one of Philips’ litigation counsel – retained Exponent. Both letters declared the retention as being related to pending and anticipated litigation. For example, the October letter states the retention was “for purposes of providing non-testifying, consulting expert services to Philips’ counsel in anticipation of litigation filed against Philips concerning certain devices that have been recalled.” Exponent’s toxicological assessment, and ultimately the Final Reports, followed.

Plaintiffs rely on four main arguments in support of their position that Exponent’s retention leading up to the Final Reports was not primarily for litigation purposes. None are persuasive.

Plaintiffs rely heavily on the fact that, since disclosing Exponent’s Final Reports to the FDA, Philips repeatedly has described Exponent as an “independent” toxicology consultant. *Ps’ Motion* at 1-2, 3-4; *Plaintiffs’ Opposition to Defendants’ Motion for Protective Order dated May 16, 2023* (“*Ps’ Opp’n*”) at 1, 3. Plaintiffs argue Philips’ characterization of Exponent as “independent” necessarily means Exponent is a business, and not a non-testifying litigation, consultant. *Ps’ Opp’n* at 3 (faulting Philips for contradicting itself by referring to Exponent as “independent” in one breath and a “consulting expert” in another breath). Plaintiffs do not support this position with any case law, and common sense undermines it. Exponent is not owned, controlled, or affiliated with Philips. The dictionary definition of “independent” includes “not subject to control by others,” “self-governing,” and “not affiliated with a larger controlling

unit.” See <https://www.merriam-webster.com/dictionary/independent>. Litigation counsel may well seek scientific assessments from non-testifying experts that are not affiliated with their client to try to ensure that consultants are, and/or are perceived to be, objective and reliable. Independence, then, is consistent with a consultant’s role as a non-testifying expert.

Plaintiffs also point to the dual role Exponent played for Defendants. Philips does not dispute it retained Exponent for roles other than non-testifying expert work, and is not trying to shield from production Exponent documents related those other roles. Plaintiffs acknowledge that an expert may serve “*both* as a trial advisor and as a business consultant (emphasis in original),” and only documents related to the latter are discoverable. *Ps’ Opp’n* at 2, citing *In re Painted Aluminum Products Antitrust Litigation*, 1996 WL 397472 (E.D. Pa. July 9, 1996) and *Marine Petroleum Co. v. Champlin Petroleum Co.*, 641 F.2d 984 (D.C. Cir. 1979) (“one may simultaneously be a litigational expert with Rule 26(b)(4) protection as to some matters and simply an unprotected actor or witness as to others”); see also *Plaintiffs’ Reply Brief in Support of its Motion to Compel dated May 23, 2023* (“*Ps’ Reply*”) at 1-2 (citing cases; when an expert has been dually designated, the non-testifying expert designation only shields material related to that designation). The question, then, is not whether Exponent had dual roles, but whether the Final Reports were produced pursuant to a non-testifying expert role or another role.

Plaintiffs contend Philips has failed to adduce evidence of the scope and nature of Exponent’s services that led to the Final Reports. They claim Philips has only made “broad and imprecise assertions” that “fall short of . . . providing any basis to determine that Exponent served as a consulting expert for purposes of litigation.” *Ps’ Opp’n* at 2, citing *Grimsley v Manitowoc Co., Inc.*, No. 1:15-cv-1275, 2017 WL 2985119, at *7 (M.D. Pa. July 13, 2017) (finding insufficient the mere assertion that a file “may contain” documents or information

protected by the attorney-client privilege or the work product doctrine). This argument turns a blind eye to the retention letters. Plaintiffs go so far as to claim the October retention letter has “no reference to the litigation” (*Ps’ Motion* at 2) – which is puzzling in light of that letter’s express reference to the retention being for the purpose of providing non-testifying, consulting expert services to Philips’ counsel “in anticipation of and in connection with litigation filed against Philips concerning [the Recalled Devices].” Plaintiffs do not provide any legal support for their apparent belief the express terms of the retention letters are insufficient.

Finally, Plaintiffs argue Defendants’ primary purpose in retaining Exponent could not have been for litigation support because of the public uses to which Philips has put the Reports, including providing them to the FDA, and referencing them on its website and even to this Court in a status conference. This argument misses the mark. The focus of the inquiry is not on how Defendants used the Exponent Final Reports *after* they were prepared – but rather on the purpose for the retention in the first place. As Plaintiffs themselves concede, the question is: “was Exponent actually serving in the role of consulting expert when it performed the work underlying the [Reports].” *Ps’ Reply* at 1. That inquiry is answered by the retention letters, and the sequence of events – the recall, then litigation, then Morgan Lewis’s retention of Exponent, then Exponent’s assessments and, ultimately, the Final Reports.

B. Philips’ Waiver Was A Limited – Not A Subject Matter – Waiver

Having determined that Rule 26(b)(4)(D) applies to the Exponent work at issue, the next question is whether Philips’ waiver was specific to the documents it disclosed, or whether it amounted to a general subject matter waiver. The parties agree Federal Rule of Evidence (“FRE”) 502(a) governs this inquiry: Philips’ waiver of any privilege as to the Final Reports will

extend to undisclosed materials only if:

- (1) the waiver is intentional;
- (2) the disclosed and undisclosed communications or information concern the same subject matter; and
- (3) they ought in fairness to be considered together.

Philips' disclosure of the Exponent Reports was intentional, and the disclosed and undisclosed documents concern the same subject matter. The only question is whether "they ought in fairness to be considered together."

The Advisory Committee Note to Rule 502(a) explains (emphasis added):

The rule provides that a voluntary disclosure . . . to a federal office or agency, if a waiver, generally results in a waiver only of the communication or information disclosed; a subject matter waiver (of either privilege or work product) is reserved for those unusual situations in which fairness requires a further disclosure of related, protected information, *in order to prevent a selective and misleading presentation of evidence to the disadvantage of the adversary.*

Plaintiffs do not take issue with Philips' representation that it produced the Final Reports, with attachments, in their entirety, that is:

- The full, unredacted Reports;
- The scientific data analyzed in the Reports, including the lab reports prepared by all of the third-party Labs retained to assess the Foam;
- All other underlying data and facts relied on in the Reports;
- The methodologies, assumptions, and techniques employed by Exponent;
- Limitations Exponent identified to its analyses; and
- Communications between Exponent and the Labs.

In short, Philips produced everything Plaintiffs would need to assess, replicate, and/or challenge Exponent's conclusions. For this reason, Philips' production was not "selective and

misleading,” and Plaintiffs’ accusations that Philips “cherry-picked” documents (*Ps’ Motion* at 4), is using the privilege as “both a sword and a shield” (*Ps’ Opp’n* at 4), and trying “to present a one-sided story to the court” (*id.*) ring hollow.

Plaintiffs do not dispute the Reports and attachments contain all the information their expert(s) would need to perform their own analyses. They instead justify their request for drafts and communications between Exponent and Philip (including its litigation counsel) in order to explore potential biases or pressures that may have been imposed by Defendants or their counsel on Exponent. *See Ps’ Motion* at 4 (“The undisclosed documents might very well demonstrate that Philips used Exponent to write reports with pre-determined assumptions and conclusions”); *id.* at 5 (“The undisclosed documents likely will show that Philips (or its counsel) had a heavy hand in writing and editing the so-called ‘independent’ reports”); *Ps’ Reply* at 3 (“Plaintiffs should be entitled to explore Exponent’s bias, the pressure that may have been put on Exponent to reach a certain conclusion, and any evidence of Exponent’s role that may belie Philips’s assertion it was acting ‘independently’”). In other words, Plaintiffs hope to uncover grounds to challenge the reliability of the Reports – not based on their content – but rather based on speculation Exponent was not truly acting independently.

Plaintiffs cite a number of subject matter waiver cases in which courts concluded under FRE 502(a) that fairness required the withholding party to supplement its prior limited disclosure. A review of these cases, however, shows none involved comparable situations. They involved some type of selective or partial disclosure that is not present here.

In *Westinghouse Elec. Corp. v. Republic of Philippines*, 951 F.2d 1414, 1418-19, 1426, 1428 (3d Cir. 1991), Westinghouse had made a *selective* disclosure of its internal investigation’s findings by disclosing them to the government, but *not* to its adversaries in civil litigation. The

court held a corporation's voluntary disclosure of summary findings from its internal investigation and audit to the DOJ and the SEC while under investigation by both agencies waived its privileges as to all adversaries. Here, Philips produced to Plaintiffs the *exact same* materials it disclosed to the government. Nothing in *Westinghouse* suggests Philips should be required to disclose drafts and otherwise privileged communications that were never disclosed to the government.

Most of the other cases on which Plaintiffs rely involved *partial* productions of selective portions of an expert's report. For example, in *United States v. Coburn*, 2022 WL 357217 (D.N.J. Feb. 1, 2022), at *7, *on reconsideration in part*, 2022 WL 874458 (D.N.J. Mar. 23, 2022), the defendant had disclosed *summaries* of interviews to the DOJ, but not the *actual* interview notes. The court – while declining to find a broad subject matter waiver as to any and all documents on the same subject – broadened the scope of the defendant's limited waiver beyond merely the interview summaries to also the actual interview notes and documents conveyed in the interview summaries or otherwise presented to the DOJ. *See also City of Capitola v. Lexington Ins. Co.*, 2013 WL 1087491, at *2 (N.D. Cal. Mar. 13, 2013) (where the plaintiff had produced only *summaries* of its engineering expert's study and correspondence paraphrasing the study's final conclusion that were favorable to plaintiff's position, the court required that, in fairness, the expert's entire investigation should be produced); *In re King's Daughters Health Sys., Inc.*, 31 F.4th 520, 528 (6th Cir. 2022) (requiring the plaintiff to produce a complete study rather than selective information about only a small portion of the data collected and analyzed by the experts). These cases are inapposite because Philips did not produce only

portions of Exponent’s investigation or reports – it produced the entirety of the Final Reports and all the data analyzed by Exponent.²

Only one case cited by Plaintiffs involved prior drafts of produced documents – *Rains v. Westminster Coll.*, No. 2:20-cv-00520, 2022 WL 4120771, at *7 (D. Utah Sept. 9, 2022). In *Rains*, the defendant’s general counsel relied on an outside counsel’s investigation in deciding to terminate the plaintiff’s employment, citing that investigation in his termination letter. In discovery, the defendant produced three different versions of a “final” report. Because of that confusing situation, the court concluded that, in fairness, the defendant should have to disclose related documents in order to determine how the different “final” versions came to exist, and which version(s) the general counsel relied on in making his decision. Here, in contrast, there is no such confusion about multiple versions of the same Report.

None of the cases on which Plaintiffs rely support the conclusion that FRE 502(a)’s fairness prong requires the production of drafts and internal communications for the sake of finding fodder to attack suspected biases of, or outside influences on, Exponent. Instead, they require that Philips produce all the data on which the Final Reports rely so that Plaintiffs have the same opportunity to have a scientific expert perform their own assessment. That is exactly what Philips has done. For that reason, under FRE 502(a) and cases interpreting it, fairness does not require that the Reports be considered along with prior drafts and internal and counsel communications.

² Plaintiffs also cite *In Re Hum. Tissue Prod. Liab. Litig.*, 255 F.R.D. 151, 158 (D.N.J. 2008), but this case involved an implied waiver question – not a general subject matter waiver question. The court analyzed whether, by raising a good faith immunity defense based on an investigation conducted by legal counsel, the defendant should be required to produce the background investigation on which that defense relied. Defendants here are not relying on advice of counsel to defend this litigation and, in any event, have produced the background information on which the Final Reports rely.

C. Plaintiffs Have Not Shown “Substantial Need” or “Exceptional Circumstances”

Having concluded the draft reports and related undisclosed communications are protected by Rule 26(b)(4)(D)’s non-testifying expert protection, and that a sweeping subject matter waiver has not been made, the next question is whether Plaintiffs have established an exception to the presumption against disclosure.

Rule 26(b)(3), the general rule on “Trial Preparation Materials,” provides a party may not discover documents prepared in anticipation of litigation unless that party “shows that it has *substantial need for the materials to prepare its case* and cannot, without undue hardship, obtain their substantial equivalent by other means.” Rule 26(b)(4)(D), the rule specifically addressing non-testifying experts, provides a party may only obtain discovery from such an expert by “showing *exceptional circumstances* under which it is *impracticable for the party to obtain facts or opinions on the same subject* by other means.”

Plaintiffs believe they have substantial need and exceptional circumstances because the draft reports and undisclosed communications “likely will tell a very different story” than the final Reports (*Ps’ Motion at 5*), and may uncover bias, pressure, or other fodder to attack Exponent’s independence and objectivity (*see* page 9 above for citations to Plaintiffs’ letter briefs).

The very language of the governing Rules renders Plaintiffs’ argument unconvincing. The “substantial need” exception focuses on the need for the party “to prepare its case,” and the “exceptional circumstances” exception is limited to where it is “impracticable for the party to obtain facts or opinions on the same subject by other means.” They do not mention possible ammunition to attack independence as a justification to force disclosure of work product, and

Plaintiffs do not cite any case cases finding such rationale to constitute “substantial need” or “exceptional circumstances.”

It is worth noting that, if Philips ultimately decides to retain Exponent as a testifying expert, Plaintiffs will have the opportunity to depose Exponent – but still would not be entitled to discover their draft reports. *See* Rule 26(b)(4)(B) (protecting from disclosure draft reports of experts). If parties are not permitted to discover draft reports of testifying experts in order to challenge the credibility of their opinions, it stands to reason such drafts by non-testifying experts would be afforded as much, if not more, protection.

Plaintiffs are on equal footing with Philips in that they have all the information underlying the Exponent Reports to retain an expert (non-testifying, if they wish) to perform the same analyses as, and to identify flaws in, the Reports. The “truth” of whether the Foam is toxic or carcinogenetic does not depend on what Philips told its litigation expert; it depends on what the science proves, and Plaintiffs are free to analyze the science and challenge Exponent’s assumptions and analyses.

V. ATTORNEY-CLIENT PRIVILEGE

In the words of the Court of Appeals for the Third Circuit, “[w]hen disclosure to a third party is necessary for the client to obtain informed legal advice, courts have recognized exceptions to the rule that disclosure waives the attorney-client privilege.” *Westinghouse Elec. Corp.*, 951 F.2d at 1424. Philips raises attorney-client privilege as a secondary basis to shield production of at least a subset of the documents at issue in the current motions, specifically, communications between Defendants’ counsel and Exponent. Defendants opposed producing any of those communications, and objected to producing a privilege log identifying their


communications with specificity. Plaintiffs reply that Philips waived any privilege for the same reasons it waived any work product production.³ Plaintiffs also assert Philips failed to timely assert the privilege. Given the conclusion that the at-issue draft reports and undisclosed communications are protected by work product and not subject to discovery, there is no need for a lengthy discussion of whether some of them also are protected by the attorney-client privilege.

VI. CONCLUSION

For the reasons set forth above, the Special Master recommends that Plaintiffs' Motion to Compel undisclosed documents related to Exponent's Reports, including draft reports and related communications, be **DENIED**, and Defendants' Motion for a Protective Order be **GRANTED**.

Date: July 5, 2023

Respectfully submitted by:



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³ The FRE 502(a) discussion above applies equally to explain why fairness does not dictate these communications between Exponent and Defendants' counsel be produced.

**IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF PENNSYLVANIA**

**IN RE: PHILIPS RECALLED CPAP,
BI-LEVEL PAP, AND MECHANICAL
VENTILATOR PRODUCTS,
LITIGATION**

This Document Relates to: All Actions

)
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) Master Docket No. 21-mc-1230-JFC
)

) MDL No. 3014
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[PROPOSED] ORDER

AND NOW, this ____ day of _____, 2023, it is hereby **ORDERED** that Plaintiffs'
Motion to Compel All Documents Related to the Exponent Reports is **DENIED**, and Defendants'
Motion for a Protective Order as to the same documents is **GRANTED**.

Joy Flowers Conti, Judge

CERTIFICATE OF SERVICE

I hereby certify that on the 5th of July, 2023, I electronically filed the foregoing Special Discovery Master's Report and Recommendation and Proposed Order re: Subpoena Served by Plaintiffs on Exponent, Inc., using the CM/ECF system which will send notification of such filing to all counsel of record.

A handwritten signature in blue ink that reads "Carole Katz". The signature is written in a cursive, flowing style. The "C" is large and loops around the "a". The "K" is also large and loops around the "z". The signature is positioned above a horizontal line.

Carole Katz, Special Discovery Master